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February 27, 2006

File No: 60117.000006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of:

Jens PETERSEN

Serial No.: 09/938,667

Filing Date: August 27, 2001

Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE AND VESICOURETAL REFLUX

Group Art Unit: 1618

Examiner: Blessing M. Fubara

Confirmation No.: 2505

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith is an amendment in the above-identified application. Fees have been calculated as shown below:

CLAIMS AS AMENDED						
	Claims Remaining After Amendment	Highest Number Previously Paid For	Extra	Rate		Amount
				Large Entity	**Small Entity**	
Number of Claims in Excess of 20	86	86		$ 50.00	$ 25.00	$ 0.00
Independent Claims in Excess of 3			1	$ 200.00	**$ 100.00**	**$100.00**
Extension Fee: a) One Month				$ 120.00	$ 60.00	$ 0.00
b) Two Months				$ 450.00	$ 225.00	$ 0.00
c) Three Months				$ 1020.00	$ 510.00	$ 0.00
d) Four Months				$1590.00	$ 795.00	$ 0.00
e) Five Months				$2160.00	$1080.00	$ 0.00
First Presentation of Multiple Dependent Claims						**$180.00**
TOTAL FEE DUE						**$280.00**

☐ No additional fee is required.
☐ A check in the amount of $_____ is attached.
☒ Charge **$280.00** to Deposit Account No. 50-0206.
☒ Charge any additional fees or credit any overpayment to Deposit Account No. 50-0206.

Respectfully submitted,

By: _____
Stanislaus Aksman
Registration No. 28,562

Victoria A. Silcott
Registration No. 57,443

SA/VAS:sac

AMENDMENT

This listing of claims will replace all prior versions and listings of claims in the Application. Please amend the claims as follows:

Listing of Claims:

1-8. (Canceled)

9. (Currently amended) A method of treating urinary incontinence comprising administering an endoprosthesis, which includes a hydrogel, ~~to~~ into a urethra or a neck of a bladder of a mammal, said hydrogel comprising about 0.5% to 25% by weight, based on the total weight of the hydrogel, of a polymer prepared by a method comprising combining acrylamide and ~~a cross-linking agent~~ methylene bis-acrylamide; wherein said hydrogel includes less than 50 ppm monomeric units, has a complex viscosity of about 2 to 90 Pas and has an elasticity modulus of about 1 to 200 Pa.

10. (Currently amended) The method according to claim 9, 54, 71 or 72, wherein the polymer is prepared by combining acrylamide and [[methylene-bis-acrylamide]] methylene bis-acrylamide in a molar ratio of 150:1 to 1000:1.

11. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel comprises less than 15% by weight of the polymer, based on the total weight of the hydrogel.

12. (Currently amended) The method according to claim [[11]] 9, 54, or 71, wherein the hydrogel comprises at least 1% by weight of the polymer, based on the total weight of the hydrogel.

13. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel has a complex viscosity of about 2 to 40 Pas.

14. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel comprises at least 80% by weight water or aqueous solution.

15. (Original) The method according to claim 9, wherein the administering comprises injecting the hydrogel.

16. (Currently amended) The method according to claim 15, wherein the injecting of the hydrogel comprises injections which include[[:]]

injections at positions 10, 2, and 6 o'clock of the cross-sectional axis of the urethra ~~for the treatment of urinary incontinence or~~

~~injections at positions 10, 2, and 6 o'clock of the cross-sectional axis of the colon or rectum for the treatment of anal incontinence~~.

17. (Currently amended) The method according to claim 9 or 54, further comprising the inclusion of cells.

18-28. (Cancelled)

29. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel comprises less than 10% by weight of the polymer, based on the total weight of the hydrogel.

30. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel comprises less than 7.5% by weight of the polymer, based on the total weight of the hydrogel.

31. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel comprises less than 5% by weight of the polymer, based on the total weight of the hydrogel.

32. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel comprises less than 3.5% by weight of the polymer, based on the total weight of the hydrogel.

33. (Canceled)

34. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel comprises at least 1.6% by weight of the polymer, based on the total weight of the hydrogel.

35. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel has a complex viscosity of about 2 to 30 Pas.

36. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel has a complex viscosity of about 2 to 20 Pas.

37. (Previously presented) The method according to claim 17, wherein the cells comprise stem cells.

38. (Currently amended) The method according to claim 17, wherein the cells allow for cellular engraftment to the surrounding tissue in the urethra ~~or *analis canalis*~~.

39-46. (Canceled)

47. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel has a complex viscosity of about 2 to 50 Pas.

48-51. (Canceled)

52. (Currently amended)[[:]] The method according to claim 9, 54, or 71, wherein the polymer is substantially comprised of cross-linked polyacrylamide.

53. (Currently amended) The method according to claim 9, 54, or 71, wherein the polymer consists essentially of a ~~polymer prepared by polymerizing acrylamide in the presence of a cross-linking agent~~ polyacrylamide crosslinked with methylene bis-acrylamide.

54. (Currently amended) A method of treating urinary incontinence comprising directly injecting a hydrogel into at least one of the conduits selected from the group consisting of ~~the~~ a urethra and a neck of a bladder, ~~rectum, and colon,~~ wherein the hydrogel comprises water or aqueous solution and about 0.5 to 25% by weight polymer having fewer than 50 ppm monomer units and ~~has~~ having a complex viscosity of about 2 to 90 Pas and an elasticity modulus of about 1 to 200 Pa, the polymer prepared by combining acrylamide and ~~a cross-linking agent~~ methylene bis-acrylamide.

55. (Currently amended) The method of claim 54 or 72 wherein the aqueous solution is a saline solution ~~and the cross-linking agent is methylene-bis-acrylamide~~.

56. (Canceled)

57. (Previously presented) The method according to claim 14, wherein the aqueous solution is a saline solution.

58-61. (Canceled)

62. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel comprises at least 75% by weight water or aqueous solution.

63. (Previously presented) The method according to claim 14, wherein the water is pyrogen free water.

64-66. (Canceled)

67. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel has an elasticity modulus of about 5 to 150 Pa.

68. (Currently amended) The method according to claim 9, 54, or 71, wherein the hydrogel has an elasticity modulus of about 10 to 100 Pa.

69. (Currently amended) The method according to claim 9, 54, or 71, wherein the elasticity modulus and the complex viscosity are related by a factor of 5.8 to 6.4.

70. (Canceled)

71. (New) A method of treating anal incontinence comprising administering an endoprosthesis, which includes a hydrogel, to a mammal, said hydrogel comprising about 0.5% to 25% by weight, based on the total weight of the hydrogel, of a polymer prepared by a method comprising combining acrylamide and methylene bis-acrylamide; wherein said hydrogel includes less than 50 ppm monomeric units, has a complex viscosity of about 2 to 90 Pas and has an elasticity modulus of about 1 to 200 Pa.

72. (New) A method of treating anal incontinence comprising directly injecting a hydrogel into at least one of the conduits selected from the group consisting of a rectum and a colon, wherein the hydrogel comprises water or aqueous solution and about 0.5 to 25% by weight

polymer having fewer than 50 ppm monomer units and having a complex viscosity of about 2 to 90 Pas and an elasticity modulus of about 1 to 200 Pa, the polymer prepared by combining acrylamide and methylene bis-acrylamide.

73. (New) The method according to claim 71 or 72, further comprising the inclusion of cells.

74. (New) The method according to claim 73, wherein the cells allow for cellular engraftment to the surrounding tissue in an *analis canalis*.

75. (New) The method according to claim 71, wherein the administering comprises injecting the hydrogel.

76. (New) The method according to claim 75, wherein the injecting of the hydrogel comprises injections which include injections at positions 10, 2, and 6 o'clock of the cross-sectional axis of the rectum or the colon.

77. (New) The method according to claim 73, wherein the cells comprise stem cells.

REMARKS

I. Statement

A personal Examiner interview was held on February 23, 2006. The interview was attended by Examiners Michael Hartley and Blessing Fubara and Applicant's representatives, Pierre Kary, Ph.D., Stanislaus Aksman and Victoria A. Silcott. Applicant thanks Examiners Hartley and Fubara for their time and attention.

Currently pending independent claims 9 and 54 were discussed in view of Russian Patent Application No. RU 2,148,957, in the name of Sknar *et al.* ("the '957 application") and U.S. Patent No. 6,486,213, issued to Chen *et al.* ("the '213 patent"). Applicant's representatives explained that the '957 application teaches the use of a polyacrylamide gel, which is described only by the name "Interfall," to treat vesicouretal reflux ("VUR"). Applicant's representatives also stated that the '213 patent, which the Examiner cited to provide some properties of a polyacrylamide hydrogel, discloses a composition for topical drug delivery that has different properties than the hydrogel used in Applicant's claimed method. However, Applicant's representatives presented a printout from the web site entitled "Interfall's Biocompatible Hydrogel" (http://www.bpg.bg/interfall/EB005140106biocompatible_gel1.htm), which indicates that the gel is patented, *inter alia*, under U.S. Patent No. 5,798,096 (of record in the present application), and a Report from the Ministry of Public Health of Ukraine, which designates "Interfall" as a 5% gel.

Moreover, Applicant's representatives presented proposed claim amendments that separate the treatment of urinary incontinence from anal incontinence and that include the location for administering the endoprosthesis to treat urinary incontinence. Applicant's representatives stated that Examples 1 and 2 of the '957 application assert that the subject was diagnosed with VUR and had complaints of urinary incontinence, but after treating for VUR, the subject had "no complaints." Conversely, the urologists consulted by Applicant stated that one would not treat urinary incontinence by treating VUR. This is underscored by the disclosure of the '957 application which states that VUR was treated by injecting the Interfall gel into the ureter ostium. To further prosecution, the proposed claim amendment includes the location of administering the endoprosthesis to clarify that the claimed method would not include administering the endoprosthesis in a ureter or a ureter ostium.

Applicant's representatives stated that administering the endoprosthesis to a urethra or a neck of a bladder to treat urinary incontinence requires the hydrogel to have the elastic properties, as claimed, that are not required for an endoprosthesis used to treat VUR. They also pointed out that there is no indication in the '957 application that hydrogels and polymers thereof have such elastic properties. In fact, the '957 application states, "[The "Interfall" gel] is permanently present in the site of inserting thereof surrounded by a thin connective tissue capsule consisting of 1-2 rows of cells of fibrocyte type and connective tissue fibers that *prevents expansion* thereof along the inter-tissue fissures . . ." *See* translation, p. 7 (emphasis added).

Examiner Hartley indicated that the claims directed to a method for treating urinary incontinence would appear to be allowable over the prior art. However, an original presentation of claims directed to a method for treating anal incontinence may possibly be subject to a restriction requirement. Applicant's representatives then stated that claims directed to anal incontinence have been pending in the application and examined (*see e.g.* claims 16, 38, 49 and 54 in the previous listing of claims); therefore, no restriction requirement is required.

Finally, Applicant's representatives raised the issue of the obviousness-type double patenting rejection of claims 9-15, 17, 29-38, 47 and 49 over claims 1, 2, 5, 7-12 and 44-50 of the '670 application. The Applicant's representatives stated that it would not be obvious to treat urinary incontinence based on claims to a bio-stable hydrogel for use as an endoprosthesis because "endoprosthesis" is very broad and may be used anywhere in a body for any purpose. Examiners Hartley and Fubara agreed to reconsider arguments regarding the double patenting rejection.

II. Amendment

Reconsideration of rejections in the Application is respectfully requested. Applicant canceled claims 33, 49, 51, 64-66 and 70 without prejudice. Applicant reserves all his rights to pursue protection for the subject matter of all canceled claims in future patent applications. Upon entry of the foregoing amendment, claims 9-17, 29-32, 34-38, 47, 52-55, 57, 62, 63, 67-69 and 71-77 will be pending. Claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 stand rejected. Claims 9-14, 16, 17, 29-32, 34-36, 38, 47, 52-55, 57, 62, 63, 67-69 are amended. New claims 71-77 are added.

Applicant respectfully requests entry of the above amendment, as discussed during the Examiner interview, and submits that the amendment does not introduce new matter. Support for the amendment to the claims and for new claims can be found throughout the specification (considered as a whole) and in the claims as originally filed. In particular, support for the amendment to claims 9, 10, 53 and 54 can be found, *inter alia*, in the specification at page 4, lines 12-16 and page 8, line 30 to page 9, line 7. Claims 10-14, 17, 29-32, 34-36, 47, 52, 53, 55, 62 and 67-69 have been amended to depend from independent claims 9, 54, 71 or 72. Claims 16, 38 and 55 have been amended to correct antecedent basis.

As discussed in the Examiner interview, new claims 71-77 are directed to a method for treating anal incontinence. Claims 71-77 correspond to claims 9, 54, 17, 38, 15, 16 and 37, respectively, which are directed to the treatment of urinary incontinence. Support for a method of treating anal incontinence can be found, *inter alia*, in the specification at page 4, lines 1-5.

Based on the above amendments, the interview and the remarks in this Supplemental Response, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

III. Double Patenting

Claims 9-15, 17, 29-38, 47 and 49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7-12 and 44-50 of copending Application No. 09/938,670 ("the '670 Application"). As stated during the Examiner interview, Applicant respectfully submits that it would not be obvious to treat urinary or anal incontinence based on claims to a bio-stable hydrogel for use as an endoprosthesis because "endoprosthesis" is very broad and may be used anywhere in a body for any purpose.

Applicant is aware of the holding in *Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC*, 68 U.S.P.Q.2d 1865 (C.A.F.C. 2003); however, the present application is distinguished from the facts in that case. First, the court looked to the specification of the two patents to determine the scope of the compared claims in an obviousness-type double patenting analysis in *Geneva Pharmaceuticals Inc.* because the claims alone did not adequately disclose the patentable bounds of the invention. *See id.* at 1875. In contrast, the claims in the applications at issue

distinctly claim the limitations that form the patentable bounds of the invention, and thus, one need not look to the specifications..

Second, the specification of the product patent disclosed only a single use for the product in *Geneva Pharmaceuticals Inc.*; this was the use claimed in the method claim of the second patent. The court concluded that the claims of the two patents were not patentably distinct. Conversely, the specification of the '670 application describes many uses for the hydrogel claimed. Therefore, the claims of the two applications are distinct.

For all the reasons discussed above and based on the identified claims of the '670 application, it would not be obvious to one of ordinary skill in the art to use the hydrogel claimed in the '670 application for a method of treating urinary or anal incontinence, and Applicant respectfully requests that the obviousness-type double patenting rejection be reconsidered and withdrawn.

CONCLUSION

For at least the reasons stated above, claims 9-17, 29-32, 34-38, 47, 52-55, 57, 62, 63, 67-69 and 71-76 are in condition for allowance. Accordingly, Applicant respectfully requests that the Application be allowed and passed to issue.

In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

It is believed that no fees are due in connection with this Supplemental Response. However, in the event it is determined by the U.S. Patent and Trademark Office that fees are due, including any fees for a petition for extension(s) of time, the Commissioner is hereby authorized to charge such fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: February 27, 2006

By: _____

Stanislaus Aksman
Registration No. 28,562

Victoria A. Silcott
Registration No. 57,443

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of:	)	
	)	
Jens PETERSEN	)	Group Art Unit: 1618
	)	
Application No.: 09/938,667	)	Examiner: Blessing M. Fubara
	)	
Filing Date: August 27, 2001	)	
	)	
Title: POLYACRYLAMIDE HYDROGEL FOR THE TREATMENT OF INCONTINENCE AND VESICOURETAL REFLUX	)	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicant submits attached Form PTO/SB/08A (modified) for consideration and requests the references cited therein be made of record by the U.S. Patent and Trademark Office ("USPTO") in the above-captioned application.

The references cited were discussed in the Examiner interview held on February 23, 2006 and are being submitted to be made of record.

Applicant respectfully points out that the submission of the listed references in this Information Disclosure Statement is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of this Information Disclosure Statement is not an indication that a search has been made by Applicant.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form PTO/SB/08A with the Examiner's initials in the left column in accordance with M.P.E.P. § 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(c)(2), this Information Disclosure Statement is believed to be submitted after the issuance of a first Office Action on the merits but before the mailing date of any action closing prosecution in the application. The Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206 the amount of $180.00 in accordance with 37 C.F.R. § 1.17(p). It is respectfully submitted that no additional fees are required for consideration of this information. However, in the event that the USPTO determines that a variance exists between the amount authorized above and the amount due, the Commissioner is hereby authorized to debit or credit such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: February 27, 2006

By: _____
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number	09/938,667
Filing Date	August 27, 2001
First Named Inventor	Jens PETERSEN
Art Unit	1618
Examiner Name	Blessing M. Fubara
Sheet 1 of 1	**Attorney Docket Number** 60117.000006

OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION YES	TRANSLATION NO
	1.	Ministry of Public Health of Ukraine, Kiev Research Institute of Hematology and Blood Transfusion, Report dated February 29, 1993.	☐	☐
	2.	Interfall's Biocompatible Hydrogel, Doctor's Information (February 22, 2006) (citing U.S. Patent. No. 5,798,096) *at* http://www.bpg.bg/interfall/EB005140106biocompatible_gel1.htm.	☐	☐
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			☐	☐
			☐	☐
			☐	☐

EXAMINER SIGNATURE | DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

MINISTRY OF PUBLIC HEALTH OF UKRAINE

Kiev Research Institute of Hematology and Blood Transfusion

29.02.1993

REPORT

on Conducted Investigations on the Study of Hemolytic Activity of Preparation "Interfall"

Samples of preparation "Interfall" made with the account o. remarks we have expressed at the first stage of work were the objects of the present research.

In the process of a set of researches carried out it has be established that under the immediate contact of the donor's bloo with the preparation "Interfall" the hemolysis manifestation is within the limits of admissible values 9.18-10.24 μmol/l which do not differ from the indices in the control samples.

Experimental blood samples being stored for 24 hours at +2 ... + 5°C, the amount of free hemoglobin in them was not changed as compared with the initial indices for the first 2 hour and was 9.81 and 10.41 μmol/l, respectively.

Thus, the preparation "Interfall" (5% gel) prepared on isoto nic solution of sodium chloride does not possess hemolytical properties and may be used in medical practice as material for making prostheses.

Head of the Laboratory of
Conservation of Components and
Homopoietic Tissue Kiev Research
Institute of Hematology and Blood
Transfusion Stat Prize Laureate
Doctor of Midicine

INTERFALL's BIOCOMPATIBLE HYDROGEL

(HYDROPHILIC POLYCRYLAMIDE)

sterile, nonpyrogenic

Home
Doctors Information
Indications
US Patent

PDF Documents
Brochure
US Patent

The New Generation in Cosmetic Corrections

NEW

DOCTOR'S INFORMATION

Gel PAAG Interfall

This preparation is registered by the Ministry of Public Health of Ukraine under No. 268/96. Patents in Ukraine: No 94086726, in Russia: No 2034465, in USA: No 5798096, in EU No: 94928547.2-2107

This gel is a colorless, transparent gel, without foreign inclusions, synthesized from acrylamide as the base by employing the unique technology the Interfall Company. It is a biocompatible material ideally suited to the features required of the materials for the above said purpose.

The correction must be performed under the operating-room conditions by following carefully the rules of asepsis and antisepsis.

DOSAGE AND APPLICATION TECHNIQUE

Proportions of the introduced material and its application technique are in compliance with the methods for injection-type endoprosthetics developed by the Interfall company and approved by the Committee for New Technologies.

STERILE

Permissible single sterilization at

CHARACTERISTICS

- the gel is NOT prone to disruption by proteolytic, lypolytic, amynolytic, and other enzymes; it causes NO local, nor general allergic reactions;develops NO hemodynamic disorders within the tissues (repletion, or emptiness of blood vessels, prehemostasis, hemostasis, thrombosis, ischemia);
- exerts NO carcinogenic effect upon the tissues;
- causes NO irritation of the surrounding tissues;
- does NOT create fibrous formations within the capsule;
- has NO toxic effect upon the organs and tissues;
- has NO hemolytic properties;
- has NO embriotoxic effect;
- does NOT resolve:
- is NOT rejected:
- does NOT dislocate within the tissues;
- does NOT hamper differential diagnostics, with the availability of modem equipment and professional skill.

RELEASE FORM

Sterile vials of 20 ml, 50 ml, and 250 ml volume.

STORAGE CONDITIONS

To be stored at room temperature

t=120°C

Shelf life -2 years

ADVERSE REACTIONS

Not a single case of such correction ever resulted into any side effects at any stage of its performance and in distant future, provided the methods of injection, recommendations as to the application were observed and indications and contraindications considered.

Send mail to interfall@bulgpharmgroup.com with questions or comments.